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HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791				
EXAMINER				
PELLEGRINO, BRIAN E				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/823,456

Applicant(s)

NAZZARO, PATRICE

Examiner

Brian E. Pellegrino

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-16,18-21,24-41,44-57,59-64 and 79-91 is/are pending in the application.
- 4a) Of the above claim(s) 81,84,87 and 90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-16,18-21,24-41,44-57,59-64,79,80,82,83,85,86,88,89 and 91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 12/30/08 have been fully considered but they are not persuasive. The Examiner would like to clarify the Applicant's comments regarding what the Examiner considered Nunez to disclose. Applicant alleged that Nunez was not believed to teach a bulbous section by the Examiner. This is incorrect, what Nunez did not explicitly disclose was to have a smaller diameter section transitioning from a bulbous section to be located on the opposite side of second smaller diameter section. For example, Nunez illustrates (Fig. 5) a small diameter and large diameter (bulbous) seamlessly woven. However, Nunez did not illustrate the second smaller diameter section on the opposite side of the large diameter section.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Yachia discloses that the prosthesis includes a graft and is thus a relevant teaching. The Examiner was relying on the teachings of Yachia solely for its structure in cross-section, a first diameter section, a bulbous section and a second diameter section on the opposite side or flanking the bulbous section. Second Nunez already provides the basis for modifying

the prosthesis since a seamless transition region is disclosed to provide a change in diameter in the prosthesis. Thus, one of ordinary skill would be highly capable of creating a prosthesis with the shape as taught by Yachia by just altering the prosthesis of Nunez to transition from the large diameter to form a second seamless transition on the second side to thus create a bulbous section in the middle or center of two smaller diameter sections.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the new limitation that "said woven portions of said first tubular end, said second tubular end and said bulbous woven section are seamlessly transitioned, with continuous warp yarns common to each of said first and second tubular ends said bulbous woven" was not found in the written disclosure.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 10, 12, 14-16, 18-21, 24-29, 31-36, 38-41, 44-56, 59-64, 79, 82, 85, 88, 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nunez et al. (5800514) in view of Yachia et al. (2004/93065). Nunez et al. show (Figs. 3, 8) an implantable graft having a flat-woven tubular portion (130) and a bulbous woven section (120)

contiguous with the first section. Nunez et al. disclose that the varying diameter implantable graft has a continuous warp yarns to form a seamless body, col. 3, lines 45-47,50,51, 54-58. It is known that a woven fabric in forming its weave has the warp yarns in a continuous length, see Edenbaum (5445599). Thus, the warp yarns in the seamless tubular prosthesis of Nunez would be continuous and common along the length of the prosthesis. Nunez et al. also disclose that the woven graft has the engagingly interlaced yarns between the bulbous end and tubular section are provided with a **seamless** transition, col. 9, lines 58-61. In order to transition from one diameter to another, Nunez discloses the bulbous section includes an increase of at least three warp yarns for every two fill yarns, col. 10, lines 46-52,64,65. Nunez also discloses that a graft can have three sections with the second section being contiguous with the first section and including a different diameter and the third section being different than the second, col. 4, lines 29-45. It can be interpreted that more longer warp yarns are used to form the bulbous portion or larger diameter, since a tubular portion has the same number of warp yarns maintained to keep a constant diameter, (col. 9, lines 12,13,16,17) and thus there is spaced apart locations where the engaging and disengaging of the threads of warp yarns with fill yarns begin and end with the bulbous area. However, Nunez et al. do not explicitly state the middle section is bulbous or that a third section has a diameter the same as the first section. Yachia et al teach (Fig. 6) a graft or stent-graft that has a bulbous section (610) for use in a peristaltic organ, paragraph 38. The two ends of same diameter flanking the central section stabilize the central section, this is known and common sense. It would have been obvious to one of

ordinary skill in the art to utilize the teaching of Yachia and include the third section of the same diameter as a first section that flanks a central section for the graft of Nunez et al. such that it better stabilizes the device and can be used in areas such as the esophagus.

Regarding claims 2,3,50,51 Nunez discloses the number of warp yarns are equal to maintain the same diameter and thus these sections would be the same, col. 9, lines 12-18.

With respect to claims 4,5,33,34,49,52,53 Nunez discloses the diameter can be about 2mm greater for the bulbous portion than the tubular portion of which can be 10mm.

Regarding claims 6,35,55 Nunez et al. also disclose the weave can be a plain, basket, twill or velour type, col. 10, lines 32-35.

With respect to claims 7,36,56 Fig. 3 shows the woven pattern is the same for the tubular portion and the bulbous section.

Regarding claim 14, the yarn can be monofilament or multifilament, col. 10, lines 15,16.

With respect to claims 15,16,18,19,38,39,59 Nunez et al. additionally disclose polymers, such as polyethylene can be used for the yarns, col. 10, lines 8,9,14.

Regarding claims 10,12,20,21,40,41,60,61 Nunez et al. disclose the yarns can be single ply, preferably have a denier from 40-300, thus it can be 70, and made of polyester and can be twisted yarns, col. 10, lines 17,18,27-31. Nunez does disclose multiple filaments, but Nunez does not explicitly disclose including 54 filament. It would

have been obvious to one of ordinary skill in the art at the time the invention was made to use 54 filaments, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claims 27-29,44-46, Nunez discloses the graft can be crimped, col. 11, lines 37-39.

With respect to claim 31, Figs. 15,16 of Nunez illustrate multi-lumen tubular structure.

Regarding claims 82,85,88,91, Nunez et al. disclose that the number of warp yarns vary as the transition goes from a smaller diameter to a larger diameter, col. 4, lines 25-27.

Claims 9,11,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nunez et al. '514 in view of Yachia et al. (2004/93065) as applied to claim 1 above, and further in view of Schmitt (5383925). Nunez et al. as modified by Yachia is explained above. However, Nunez in view of Yachia fail to disclose the use of different yarns or its properties. Schmitt teaches that different yarns (inherently possessing different deniers and densities) can be used in vascular grafts to provide different structural characteristics, col. 3, lines 63-66. It would have been obvious to one of ordinary skill in the art to use different yarns as taught by Schmitt with the graft of Nunez as modified by Yachia such that it provides a more compatible and versatile prosthesis capable of accommodating the patient's anatomical needs.

Claims 30,37,57,80,83,86,89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nunez et al. '514 in view of Yachia et al. (2004/93065) as applied to claims 1,32,35,49,55,79 above, and further in view of De Paulis (6352554). Nunez et al. in view of Yachia is explained supra. However, Nunez as modified by Yachia et al. fail to disclose the portion of the graft being bulbous has a different pattern or includes a valve. De Paulis teaches (Fig. 5) a vascular graft having a valve in a bulbous, different pattern section of a graft. De Paulis also teaches that the different pattern (col. 5, lines 28-30) enables the graft to enable pressure to be reduced at the coronary ostia, col. 6, lines 42-45. DePaulis also shows (Fig. 2) the bulbous portion can be formed such that it is generally spherical to accommodate the anatomy of where it is placed. It would have been obvious to one of ordinary skill in the art to use a different pattern and valve as taught by De Paulis in the graft of Nunez et al. as modified by Yachia et al. such that it can be used in the coronary ostia when repairing an aorta. Additionally, it would have been obvious to one of ordinary skill in the art to form the bulbous portion with a generally spherical shape as taught by DePaulis in the graft of Nunez et al. as modified by Yachia et al. such that it more closely matches the anatomy of where it is implanted.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738